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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/961,403	09/25/2001	Holger Hess-Stumpp	SCH-1789	5513

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EXAMINER

WHISENANT, ETHAN C

ART UNIT PAPER NUMBER

1634

DATE MAILED: 04/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/961,403

Applicant(s)

HESS-STUMPP ET AL.

Examiner

Ethan Whisenant, Ph.D.

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) 2 and 3 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 1 and 4 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 and 9.
- 4) ☒ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

DETAILED ACTION

1. The applicant's election of Group I (**Claims 1 and 4**) with traverse in paper no.11 is acknowledged. Paper no. 11 was filed 03 OCT 02. Claims 2-3 are withdrawn from further consideration as being directed toward a non-elected invention. The claims currently being prosecuted are 1 and 4.

The traversal of the restriction requirement is based on the applicant's contention that it is not a burden on the examiner to search all of Groups I -III. The applicant's argument has been fully and carefully considered but is not deemed to be persuasive. A *prima facie* case of burden has been shown because the three inventions have acquired a separate status in the art as shown by their different classification. Because the restriction requirement is deemed proper it is herein made **FINAL**.

DRAWINGS / SPECIFICATION

2. The specification fails to comply with 37 CFR § 1.74. To what does the phrase "Figure 2" at the top of the second page marked "[Key to Table]" refer.

SEQUENCE RULES

3. This application complies with the sequence rules and the sequences have been entered by the Scientific and Technical Information Center.

35 USC § 101

4. 35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title".

Claim Rejections - 35 USC § 101

- 5.** **Claim(s) 4** is/are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. Claim 4 is nonstatutory because "the use of" is not a patentable category under 35 U.S.C. § 101.

CLAIM OBJECTIONS

- 6.** **Claim(s) 4** is/are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Please note that Claim 4 is dependent on Claim 3, a claim which has been withdrawn from prosecution.

35 USC § 112- 2ND PARAGRAPH

- 7.** The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

CLAIM REJECTIONS under 35 USC § 112- 2ND PARAGRAPH

- 8.** **Claim(s) 1** is/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear from the claim if the amount of the gene product(s) recited in the Markush group is increased or decreased in the patient sample as compared to the control. See the last three lines of Claim 1. However it appears from the specification that the applicant has discovered that these gene products are either decreased or increased depending on the phase. The claim should be clarified to make clear what is intended.

35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that may form the basis for rejections set forth in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) The invention was described in --

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a)

Claim Rejections under 35 USC § 102

10. Claim(s) 1 is/are rejected under 35 U.S.C. 102(b) as being anticipated by Kauma (1988).

Kauma et al. teach a method for the *in vitro* diagnosis of endometriosis wherein the amount of serum fibronectin is measured in patient samples and wherein 3X the amount of fibronectin is detected in samples from patients with endometriosis as in controls. Therefore, Kauma et al. teach a method for the *in vitro* diagnosis of endometriosis comprising all of the limitations recited in Claim 1.

Conclusion

11. Claim(s) 1 and 4 is/are rejected and/or objected to for the reason(s) set forth above.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (703) 308-6567. The examiner can normally be reached Monday-Friday from 8:30AM -5:30PM EST or any time via voice mail. If repeated

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attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

The fax number for this Examiner is (703) 746-8465. Before faxing any papers please inform the examiner to avoid lost papers. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989). Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to be 'E. Whisenant', with a stylized, cursive script.

Ethan Whisenant, Ph.D.
Primary Examiner